# Pragmatic randomised controlled trial of an allergy intervention for children aged 6 to 16 with asthma and rhinitis in general practice

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# Pragmatic randomised controlled trial of an allergy intervention for children aged 6 to 16 with asthma and rhinitis in general practice

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**Abstract**

Background:

It is widely believed that for allergic rhinitis and asthma, avoidance of specific triggers can improve symptom control. Whilst many children with asthma or rhinitis are sensitised to airborne allergens, primary care diagnostic and management decisions are often made without a detailed history of the allergic triggers or allergy testing. Thus, treatment decisions are empirical and allergen avoidance advice is either not given or, if given, not tailored to the child's sensitivities.

Objective:

To ascertain whether allergy assessment and tailored advice in General Practice enhances outcomes of children with asthma and rhinitis.

Method:

Pragmatic RCT of allergy intervention (structured allergy history, skin prick testing and appropriate allergy avoidance advice) versus usual care in children with asthma and/or rhino-conjunctivitis. A blinded observer assessed outcomes at 12 months. Main outcome measures were symptom scores and disease-specific health-related QoL. Secondary outcomes were health care utilisation, days unable to pursue usual activities, and self-rated improvement.

Results:

335 participants were randomised to formal allergy assessment or normal care. There were no differences in participants' demographic or clinical characteristics at baseline (all $p>.05$). At 12 months, participants receiving the allergy intervention had fewer rhinitis symptoms (MD -3.14, 95% CI -6.01, -0.81) and an improvement in QoL (MD -0.50, 95% CI 0.32, 0.68). There were no significant changes in asthma symptoms, health care utilisation or number of days unable to pursue usual activities.

Conclusion:

Amongst children with known asthma and/or rhinitis in primary care, taking a structured allergy history with skin prick testing and tailored advice on allergy avoidance resulted in reduced symptoms of rhinitis and improved QoL.

**Key words:**

asthma, allergy assessment, evaluation, quality of life, rhinitis, skin prick testing, symptoms

**Running title:** Allergy intervention for children with asthma or rhinitis

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**Abbreviations:**

| | |
|---|---|
| FEV1 | Forced Expiratory Value in one second |
| FVC | Forced Vital Capacity |
| GP | General Practitioner |
| PN | Practice Nurse |
| PEFR | Peak Expiratory Flow Rate |
| QoL | Quality of Life |
| SPT | Skin Prick Test |
| RCT | Randomised Controlled Trial |

**Background**

Allergic diseases are a common reason for consulting UK General Practitioners, representing up to 6% of all consultations and accounting for 10% of primary care prescribing costs. [1] Asthma & rhinitis are two of the most common chronic childhood diseases in the UK. [2] These conditions substantially impact on children's quality of life (QoL) [3] and their school performance. [4] The majority of children with asthma and/or rhinitis have underlying allergies. In patients with allergies, avoidance of specific triggers can reduce symptoms and the need for medication. However, most primary care diagnostic

and management decisions are made without obtaining a detailed history or performing allergy tests. Thus, treatment decisions are empiric and allergen avoidance advice is either not given or is not specific to the child's problem. It has been suggested that the introduction of allergen-specic testing such as skin prick tests (SPT) into General Practice could improve the cost-effectiveness of asthma & rhinitis care through appropriate targeting of medication and allergy avoidance advice.

Recent reviews of allergy services have highlighted major shortcomings of the allergy services provided throughout the UK. [1] The solution to this deficit lies in part with the development of a larger cadre of allergy specialists, but there is also a need to develop improved allergy care within primary care services. Descriptive studies in adults confirm the feasibility of allergy assessment in a non-specialist setting and its potential to avoid inappropriate allergy avoidance advice. [5,6] However, a subsequent randomised trial of formal allergy assessment in adults with established asthma and rhinitis did not show any significant improvements in symptoms and outcomes. [7] As these previous studies have only looked at adult patients it would be unwise to extrapolate the findings to the paediatric population without further age-specific studies.

In this trial we investigated whether assessment of allergic status (structured allergy history and skin prick testing) in General Practice together with providing appropriate advice on allergy avoidance enhances the health and wellbeing of children with asthma or rhinitis.

***Methods***

***Setting:***

General practices in two counties in the South East of England (East Sussex and West Sussex).

***Design:***

Pragmatic single-blinded randomised controlled trial (RCT) of allergy intervention (structured allergy history + skin prick testing (SPT) + appropriate advice on allergy avoidance). After baseline assessment, 335 children aged 6-16 years were randomised to receive the allergy intervention or usual care.

***Study Enrolment:***

Twenty general practices used their electronic patient records to identify patients aged 6 to 16 years with a diagnostic label of asthma, rhinitis or hay fever. Children were excluded if they had had SPT in the preceding two years, were suffering from a serious chronic or terminal illness, their parents did not speak English, or it was known that the family were moving away from the area in the next 12 months. To ensure that the diagnoses were still active, children were only invited if they had one or more problem-related consultations in the preceding year. The General Practitioner's letter of invitation included two information sheets, one for the parents and another for the child or adolescent. A postage paid envelope was provided for response. Those parents who expressed interest in in the study were contacted by the study-trained general practice nurse to confirm eligibility. Prior to the baseline assessment appointment parents and children completed a questionnaire booklet about rhinitis and asthma symptoms [8] and condition-related QoL. [9] Consent and assent to participate in the trial were obtained by the practice nurse. The parent or guardian of each

child signed a consent form and, if the child was aged between 13-16 years, their agreement to participate was confirmed by completion of a form of assent. Recruitment was conducted between November 2010 and October 2011.

***Baseline information:***

Data were collected on demographics (age, gender, ethnicity), clinical data (height, weight and diagnoses), use of primary and secondary health services for asthma and rhinitis related problems in preceding 12 months and the number of days in the last month on which the child was unable to go to school or undertake usual activities because of ill health. Spirometry ($FEV_1$, peak expiratory flow and FVC) was repeated three times using a standardised method and the best of three values were utilised in analysis[10].

***Randomisation:***

Children were randomised to formal allergy assessment or usual care (empirical treatment for 12 months and the opportunity for a structured allergy assessment on trial completion). Randomisation was blocked and stratified by General Practice.

***Intervention***

The intervention was a structured allergy history, skin prick testing, test interpretation and relevant advice on allergy avoidance. The general practice nurses all received three hours training in structured allergy assessment (history, skin prick testing and its interpretation) and were provided with written instructions on skin prick testing and access to senior clinicians (AJF or SM) if needed.

A structured allergy history was taken and documented using a proforma. The questions reviewed information on self-reported allergies, the duration and severity of asthma and/or rhinitis,

exacerbating factors, personal history of atopy, history of atopy in first degree relatives (parents and siblings), exacerbating circumstances (seasonality, time of day, indoors vs outdoors), exposure to pets, dust and mould.

Skin prick testing (SPT) to seven common aero-allergens was performed using standardised allergy extracts (house dust mite (Dermatophagoides pteronyssinus), tree pollen, mixed grass pollens, cat dander, dog dander) and two moulds (Aspergillus and Alternaria alternata). Positive (histamine) and negative (saline) controls were used. SPTs were performed on the volar surface of the forearm with 1mm-prick lancets. Wheal diameters were recorded after 15 minutes, as the arithmetic mean of the maximum diameter and perpendicular diameter. A mean wheal diameter greater than or equal to 3mm was considered a positive result (99% specificity).[11]

Advice on allergen avoidance was provided following interpretation of allergy history and SPT results. A positive history and positive skin result were needed for a diagnosis of allergy. Relevant allergen avoidance advice was given verbally and reinforced with a leaflet. The leaflets were the same as those used in the local hospital allergy clinic and were specific to tree and grass pollens, to pets (including cats and dogs), to house dust mite or to mould.

**Outcome measures**

Primary outcomes were asthma and rhinitis symptom scores and disease-specific health-related QoL. Secondary outcomes were health care utilisation, days unable to pursue usual activities and parental- and self-rated improvement.

***Rhino-conjunctivitis and asthma symptom score*** [8]

This score assesses symptoms of asthma and rhino-conjunctivitis. The symptoms of these two interdependent syndromes are scored in two domains; 11 items form the *rhinitis scale,* which asks about eye (3), nose (4) and sinus symptoms (4), and nine items form the *asthma scale,* which assesses day and night experiences of cough (2), wheeze (2), sputum production (2) and shortness of breath/chest tightness (3). All symptoms are scored on a five point scale from none (0) to severe (4). Items are weighted equally and are summed to create a score for each domain and a total symptom score, with higher scores indicating more symptoms.

***Paediatric Allergic Disease Quality of Life Questionnaire (PADQLQ)*** [9]

This self-administered health-related QoL questionnaire encompasses effects of allergic disease on a child's or teenager's eyes, ears, nose, lungs, skin, emotions, and everyday activities. The questionnaire has 26 items spread over 3 domains; practical problems (8), symptoms (15) and emotional problems (3). Patients score their experiences of their previous week on a 7-point scale (0=not troubled to 6=extremely troubled). Individual items are weighted equally and the questionnaire is analysed directly from the scores recorded. Results were expressed as the mean score per domain. Overall QoL is estimated from the mean score of all items, with higher scores indicating greater impairment of QoL.

***Frequency and duration of follow up***

Control and intervention participants were followed up at monthly intervals for one year from their baseline visit with a questionnaire that asked about the number of days that they had been unable to go to school or pursue normal activities. After 12 months all participants were invited to a follow up appointment with a research nurse who was blinded to the study arm they were allocated to. At this visit the participants again completed symptom scores and the allergic disease QoL questionnaire and

spirometry. Once the final assessment was complete, participants in the control arm were able to undergo formal allergy assessment if they wished.

***Sample size calculation***

The sample size calculation, based on QoL measurements, estimated a sample size of 105 participants in each arm would be sufficient to detect a clinically significant reduction of 0.5 (assuming a standard deviation of 1.1) at the 5% level of significance with 90% power. This sample size was estimated to be sufficient to detect a 15 percent point difference in rates for the binary response variable assessing patients' subjective assessment of improvement (improved/not improved). Allowing for 33% loss to follow up required 140 recruits in each arm.

***Data Analysis***

Data was manually entered into SPSS version 22, cleaned and all variables assessed for outliers. A frequency check was performed for the response variables and any discrepancies were checked against the case records. Twenty per cent of the data was double entered: the pre-defined minimum accuracy rate was 98%, and as this was achieved no further double data entry was undertaken. Baseline demographic characteristics were compared between the intervention and control groups using t-tests for continuous data and chi-square for binary data. Where the data did not satisfy the parametric assumptions non-parametric tests were applied. The difference in pre-test and post-test measures for the Likert scale data QoL instrument and symptom scores were analysed using Mann Whitney U Test. The comparison between the intervention and control groups were analysed using Analysis of Covariance (ANCOVA) controlling for baseline scores on each outcome. The significance level for all tests was $p< 0.05$.

Ethical approval for the study was obtained from the Scotland A Research Ethics Committee (ref: 02/10/013). The protocol for this study was published on the UK CRN website (trial number 10034).

**Results**

Three hundred and thirty five participants were recruited from 19 General Practices in Sussex and randomised, 167 patients to the control arm and 168 to the intervention arm (Figure 1). The demographic characteristics of the two groups showed no significant differences in age, gender, ethnicity, height or weight. Intervention and control participants were also comparable with respect to clinical characteristics and use of health services for asthma and or rhinitis in the preceding 12 months (Table 1). The majority of participants had both asthma and rhinitis (54%), 22% rhinitis alone and 24% asthma alone.

Three hundred and thirteen participants (93%) completed the trial. Completers and non-completers did not differ on any demographic or clinical characteristics. Compared to controls, and controlling for baseline scores, intervention participants reported a significant reduction in rhinitis specific symptoms (MD -2.19, 95% CI -3.88, -0.50) and overall symptoms (MD -3.14, 95% CI -6.01, -0.81), but not asthma specific symptoms (Table 2). Intervention participants also reported significant reductions in impaired QoL both overall (MD -0.50, 95% CI -0.68, -0.32), and in the separate domains of practical problems, symptoms and emotional problems (Table 2). The QoL results have clinical importance, as well as statistical significance, as the minimal clinical important difference for the PADQLQ is 0.3.

On completion, there was no significant difference between intervention and control participants and their parents reporting that either asthma or rhinitis/hayfever had improved, worsened or stayed the same (Table 3).Similarly there were no significant differences between intervention and controls in respect to numbers of days unable to pursue usual activities in the last month (MD -0.08, 95%CI -0.16,

0.00), GP consultations (OR 0.73, 95% CI 0.46, 1.14) or hospital attendances in the previous 12-months (OR 0.83, 95% CI 0.37, 1.86). The majority (86%) of intervention participants stated they would recommend skin prick testing to a friend.

At baseline, 71% participants suspected an allergic trigger for their symptoms. The most common suspected trigger was grass pollen (46%), followed by HDM (37%), cat (30%), tree pollen (23%), dog (18%) or mould (7%). After formal allergy assessment there were 52 children (31%) in whom new triggers were identified, i.e. a trigger identified on structured history and confirmed by SPT that had not been suspected by the parent or child when self-reporting suspected allergies (Figure 2). Thirty six participants had one new trigger identified, 15 had two new triggers and one had three. Conversely suspected triggers were not confirmed by skin prick testing in 69 patients (41%). Overall 127 participants (76%) had one or more aeroallergen trigger.

## Discussion

### *Statement of principal findings*

In this pragmatic single blind randomised controlled trial of an allergy intervention (structured allergy history & skin prick testing & tailored advice on allergy avoidance) versus usual care in children with a working diagnosis of asthma and/or rhino-conjunctivitis at 12-months, participants receiving the allergy intervention reported a reduction in symptoms (MD -3.14, 95% CI -6.01, -0.81) and an improvement in QoL (MD 0.50, 95% CI 0.32, 0.68). When symptoms were analysed separately for rhinitis- and asthma-specific symptoms, only the observed reduction in rhinitis symptoms was statistically significant. There were no significant differences in the secondary outcome measures of health service utilisation, days unable to pursue normal activities, or perceived benefit.

***Strengths and weaknesses***

The study was rigorously designed and participants were followed up for one year to reduce the impact of seasonal variation of symptoms. We recognise that randomising by patient rather than by practice may introduce contamination and reduce the differences observed between groups. However, there is very little evidence that contamination actually occurs in trials when practitioners use a structured approach to health care delivery. Trials of the management of acute minor illness conducted in primary care[12] and the Family Heart Study[13] found no evidence of intra-practice contamination. The recruitment of only one child from each household also reduced the risk of controls being influenced by the intervention. Nonetheless we acknowledge that those randomised to routine care may have become more attentive to allergen avoidance after recruitment.

The impact of the intervention may have been reduced as we did not review and confirm the diagnosis of asthma and/or rhinitis before intervention. It is recognised that environmental tobacco smoke can impact on symptom provocation and treatment responses[14] but as we did not ask about this exposure at the baseline assessment, we cannot comment on the equivalence of our two groups in this respect. Allergen avoidance behaviour was not assessed so it is not known to what extent the intervention impacted on this behaviour. However, ultimately it is the impact of an intervention on patient outcomes (symptom control and quality of life), rather than processes (such as allergen avoidance), that are of importance. We recognise that a negative skin prick test, ruling out an allergic aetiology, may be beneficial but does not require allergen avoidance.

In this study we used an existing nurse member of the primary care team to provide the intervention rather than an external peripatetic nurse. We envisaged that this is how such an intervention could be readily incorporated in practice if the intervention was worthwhile, given the universal involvement of PNs in the management of chronic disease, including asthma. Our intervention model also fits with the diversification of providers that has been promoted as an approach towards providing an

accessible and sustainable allergy service and allowing specialists to focus their expertise on patients with complex problems.[15]

The intervention was focussed on formal allergy assessment, leading to tailored advice on removal or avoidance of allergic triggers. It did not include other characteristics of good practice such as age-appropriate written personal management plan, information on charities, websites and patient support groups and/or patient/parent education, all of which are incorporated into the Royal College of Paediatrics and Child Health care pathways.[16] A case could also be made for professional education in parallel, as it is well recognised that allergy training is lacking in both undergraduate and post graduate medical curricula in the UK. [17, 18]

Reasons for a negative outcome in asthma symptoms must include the possibility that 12 months is not sufficient to achieve the full impact of avoidance measures (such as removing a pet from the household). Whilst extreme forms of allergen avoidance have been effective in other studies, for example, admission to hospital for prolonged periods or relocation to altitude, where house dust mites cannot grow due to the low absolute level of humidity [19, 20] there is very little evidence of any impact on asthma symptoms from the type of allergen avoidance measures that are practical in suburban homes at sea level. [20, 21] The recruitment of this broad spectrum of patients was appropriate as it was a pragmatic trial designed to assess the impact of the intervention in routine practice in the community.[22] The invitations to participate in the trial were based on the diagnostic codes without any additional screening for symptoms severity. It is possible that the impact of the intervention might have been more pronounced if it had focused on children with more severe disease, or only children with rhinitis. Further trials and economic evaluations are needed to ascertain whether the benefits of a structured allergy intervention could be of greater benefit if used in a more targeted manner in primary care. In conclusion, this well constructed, single-blind, pragmatic study supports the introduction of a general practice-based allergy assessments for

children with asthma and /or rhinitis to reduce the symptoms of rhinitis and to improve health related QoL.

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**Authors' contribution:**

The project devised by HS, AJF and SM. Patient recruitment, data collection, and data analysis were co-ordinated by CJ and DH, analysed by SG and CJ. All authors contributed to data interpretation and writing of the manuscript.

**Conflict of interest:**

The authors declare they have no conflicts of interest.

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Table 1: Baseline demographic and clinical characteristics for intervention and control participants

| | **Control N=167** | **Intervention N= 168** | **P value (t-test/$\chi^2$)** | **Total N=335** |
|---|---|---|---|---|
| **Demographic characteristics** | | | | |
| Mean age in years (SD, range) | 11.56 (2.78, 6-16) | 11.26 (2.72, 6-16) | .27 | 11.43 (2.75) |
| Gender *% male* | 56.3 | 57.7 | .88 | 57.0 |
| Ethnicity *% white British* | 91.0 | 88.7 | .37 | 89.9 |
| **Clinical characteristics** | | | | |
| Mean height in cm (SD) | 151.20 (16.48) | 149.98 (15.97) | .49 | 150.59 (16.21) |
| Mean weight in kg (SD) | 45.12 (15.36) | 44.97 (16.60) | .93 | 45.05 (15.97) |
| % Rhinitis only (seasonal +/or perennial rhinitis) | 21.6 | 22.2 | | 21.9 |
| % Asthma & Rhinitis | 52.1 | 55.7 | | 53.9 |
| % attending hospital (inpatient, outpatient or A&E visit) for asthma/rhinitis related problem in previous 12 months | 7.2 | 6.0 | .83 | 6.6 |
| % attending GP or Practice nurse in previous 12 months | 99.4 | 100.0 | .49* | 99.7 |
| Mean (SD) number of days in last month when unable to pursue usual activities due to asthma/rhinitis | .62 (1.75) | .72 (2.51) | .67 | .67 (2.16) |
| Lung Function FEV1 % predictedFVC % predicted | 88.54 (14.65)88.21 (14.64) | 87.15 (15.83)86.92 (16.55) | .41 .45 | |

*Fisher's exact test

Table 2: Symptom scores assessed by Wasserfallen Symptom Score Questionnaire (SSQ) and disease specific quality of life questionnaire (PADQLQ). Results are presented for each domain and overall, pre and post-intervention (n=313)

| | | | | | |
|---|---|---|---|---|---|
| ***Symptom scores*** | | | | | |
| | | **Intervention Mean (SD)** | **Control Mean (SD)** | **Mean difference [95% CI]** | **P (ANCOVA)** |
| **Rhinitis** | **Baseline** | 11.69 (8.17) | 11.77 (8.08) | -2.19 [-3.88, -0.50] | .005 |
| | **Post intervention** | 8.57 (7.18) | 10.76 (8.04) | | |
| **Asthma** | **Baseline** | 5.44 (6.06) | 6.19 (5.80) | -1.24 [-2.51, 0.03] | .115 |
| | **Post intervention** | 4.25 (5.41) | 5.49 (6.03) | | |
| **Overall score** | **Baseline** | 17.13 (12.18) | 17.97 (11.48) | -3.41 [-6.01, -0.81] | .010 |
| | **Post intervention** | 12.83 (11.25) | 16.24 (12.22) | | |
| ***Quality of Life scores*** | | | | | |
| **Practical problems** | **Baseline** | 1.11 (1.00) | 1.30 (.96) | -0.34 [-0.54, -0.14] | .004 |
| | **Post intervention** | 0.74 (.78) | 1.08 (.99) | | |
| **Symptoms** | **Baseline** | 1.31 (1.05) | 1.49 (.94) | -0.35 [-0.56, -0.14] | .004 |
| | **Post intervention** | 1.00 (.87) | 1.35 (1.03) | | |
| **Emotional problems** | **Baseline** | 0.85 (1.13) | .97 (1.10) | -0.26 [-0.47, -0.05] | .037 |
| | **Post intervention** | 0.59 (.86) | .85 (1.01) | | |
| **Overall score** | **Baseline** | 1.20 (.97) | 1.37 (.89) | -0.50 [-0.68, -0.32] | .002 |
| | **Post intervention** | 0.87 (.77) | 1.37 (.89) | | |

Table 3: Self- and parental -assessment retrospective, subjective assessment of asthma, rhinitis or hay fever during the 12 months of the trial

| | | Intervention (n=158) | Control (n=155) | P (Kendall's Tau) |
|---|---|---|---|---|
| **Asthma** | Worsened | 34 | 32 | .492 |
| | Same | 6 | 13 | |
| | Improved | 118 | 109 | |
| | N/A | 0 | 1 | |
| **Rhinitis/ hayfever** | Worsened | 38 | 45 | .727 |
| | Same | 19 | 13 | |
| | Improved | 100 | 97 | |
| | N/A | 1 | 0 | |
| **Asthma** | Worsened | 31 | 27 | .466 |
| | Same | 2 | 13 | |
| | Improved | 110 | 99 | |
| | N/A | 15 | 16 | |
| **Rhinitis/ hayfever** | Worsened | 33 | 36 | .393 |
| | Same | 24 | 23 | |
| | Improved | 84 | 76 | |
| | N/A | 17 | 20 | |

Figure 1: Consort diagram

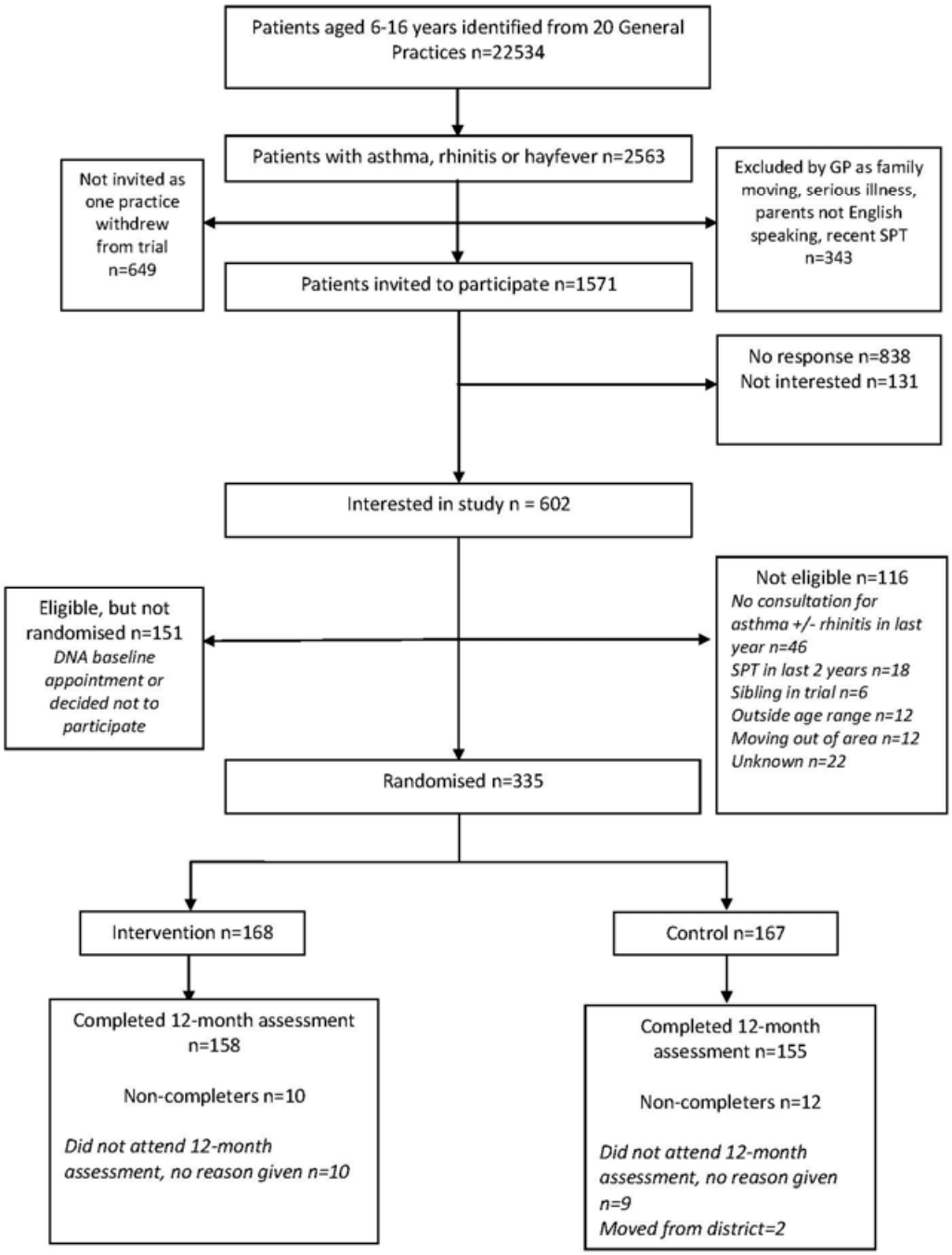

Figure 2. Shifts in participants understanding of their allergy status (n=168)